In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 14-1212V
Filed: September 9, 2022
UNPUBLISHED

ALICIA SKINNER-SMITH, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Horner Tetanus, Diphtheria, Acellular Pertussis ("Tdap") Vaccine; Cause in Fact; Cellulitis; Chronic Fatigue Syndrome ("CFS"); Motion for Reconsideration; Denial

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for petitioner.
Terrence Kevin Mangan, Jr., U.S. Department of Justice, Washington, DC, for respondent.

ORDER DENYING MOTION FOR RECONSIDERATION[1]

On December 17, 2014, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that the tetanus, diphtheria, acellular pertussis ("Tdap") vaccine that petitioner received on February 6, 2012, caused her to suffer an abscess, pain, and related injuries that became chronic. (ECF No. 1.) By the time of the hearing held in this case in May of 2021, petitioner had clarified that the chronic injury she alleges is Chronic Fatigue Syndrome ("CFS"). (ECF No. 132.) On August 15, 2022, I issued a ruling on entitlement, finding petitioner entitled to compensation for her alleged injection site injury (determined to be cellulitis), but not her alleged CFS. (ECF No. 160.) On September 6, 2022, petitioner timely filed a motion for reconsideration of the ruling on entitlement. (ECF No. 162.) For the reasons discussed below, petitioner's motion is **DENIED**.

[1] Because this order contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

I. Legal Standard

Under the Vaccine Rules, motions for reconsideration are governed by Vaccine Rule 10(e). Either party may file such a motion within 21 days of the issuance of a special master's decision so long as judgment has not entered and no motion for review has been filed. The special master may seek a response from the nonmoving party, but is only required to do so if granting the motion and reaching a different result. Vaccine Rule 10(e)(2) and (3)(A)(ii). Thus, because I am denying petitioner's motion, no response is necessary.

Special masters have the discretion to grant a motion for reconsideration if to do so would be in the "interest of justice." Vaccine Rule 10(e)(3). It has previously been noted, however, that there is little guidance interpreting Vaccine Rule 10(e)(3) beyond the conclusion that it is within the special master's discretion to decide what constitutes the "interest of justice" in a given case. *See Krakow v. Sec'y of Health & Human Servs.*, No 03-632V, 2010 WL 5572074, at *3 (Fed. Cl. Spec. Mstr. Jan. 10, 2011) (granting reconsideration of motion to dismiss case for failure to prosecute). Generally "[a] court may grant such a motion when the movant shows '(1) that an intervening change in the controlling law has occurred; (2) that previously unavailable evidence is now available; or (3) that the motion is necessary to prevent manifest injustice.'" *System Fuels, Inc. v. United States*, 79 Fed. Cl. 182, 184 (2007) (quoting *Amber Resources Co. v. United States*, 78 Fed. Cl. 508, 514 (2007)). Granting such relief requires "a showing of extraordinary circumstances." *Caldwell v. United States*, 391 F.3d 1226, 1235 (Fed. Cir. 2004) (citation omitted), *cert. denied*, 546 U.S. 826 (2005).

Special masters have previously concluded with regard to Vaccine Rule 10(e) that "the 'interest of justice' standard is likely less onerous than 'manifest injustice.'" *Krakow*, 2010 WL 5572074, at *5. Nonetheless, "a motion for reconsideration should not be used to gain a second opportunity to argue what was already decided." *Chuisano v. Sec'y of Health & Human Servs.*, No. 07-452V, 2013 WL 6234660, at *20 (Fed. Cl. Spec. Mstr. Oct. 25, 2013) (citing *Fillmore Equipment of Holland, Inc. v. United States*, 105 Fed. Cl. 1, 9 (2012)). A party seeking reconsideration "must support the motion by a showing of extraordinary circumstances which justify relief." *Fru–Con Constr. Corp. v. United States*, 44 Fed. Cl. 298, 300 (1999). The motion for reconsideration "must be based 'upon manifest error of law, or mistake of fact, and is not intended to give an unhappy litigant an additional chance to sway the court.'" *Prati v. United States*, 82 Fed. Cl. 373, 376 (2008) (quoting *Fru–Con Constr. Corp.*, 44 Fed. Cl. at 300).

Additionally, petitioner files four new exhibits that purport to support petitioner's arguments on reconsideration. (ECF No. 163; Exs. 39-42.) As a threshold matter, consideration of new evidence upon reconsideration is generally limited to evidence that was not previously available. *See*, *e.g.*, *Cozart v. Sec'y of Health & Human Servs.*, No. 00-590V, 2015 WL 6746499, at *4 (Fed. Cl. Spec. Mstr. Oct. 15, 2015) ("The additional evidence that petitioners presented is not new evidence; rather, it is an article that was available to petitioners at the time this case went to hearing. The argument that

petitioners did not deem this article relevant until the undersigned issued her decision is not proper grounds for reconsideration of the undersigned's decision."). Petitioner has not established—nor even asserted—that any of this newly filed evidence was previously unavailable.[2] Accordingly, none of these exhibits is properly presented as a basis for reconsideration.

Nonetheless, the principle of fundamental fairness that governs the admission of evidence in this program (*see* Vaccine Rule 8(b)(1)) requires a special master to carefully consider whether additional evidence should be admitted, even after the evidentiary record has closed. *Horner v. Sec'y of Health & Human Servs*., 35 Fed. Cl. 23, 27 (1996) (explaining that "[i]n light of the critical importance of the record and the possibility of authentication, the Court finds that fundamental fairness requires that the special master determine whether the document is genuine and admit the document if he confirms its authenticity . . . Although consideration of the vaccine record at this point is inconvenient, it is not fundamentally unfair to the respondent.")

The Court of Federal Claims has recognized four factors that should be considered when determining whether it is appropriate to reopen the record on entitlement to consider subsequently filed evidence. *Vant Erve v. Sec'y of Health & Human Servs.*, 39 Fed. Cl. 607 (1997), *aff'd*, 232 F.3d 914 (Fed. Cir. 2000). Those four factors are: (1) the nature of the proffered new evidence; (2) the prejudice to the parties; (3) the length of the delay; and (4) the reason for the delay. *Id*. at 612. Importantly, however, the factors do not warrant equal weight, with the nature of the proffered evidence being the "paramount test." *Id*. The first prong examining the nature of the evidence looks to "the extent to which the new evidence is both relevant and affective of outcome." *Id*. The second prong examining prejudice to the parties should focus on "evaluating the practical consequences of reopening on the nonmoving party's ability to re-establish its case." *Id*. at 614. The third and fourth prongs, the length and reason for delay, are of lesser importance, but should be considered in connection with the other factors by examining "whether the delay has prejudiced the nonmoving party and the identity of the party that caused the delay." *Id*.

II. Discussion

Petitioner asserts that the testimony of her expert, Dr. Lapp, and the medical opinion of her treating physician, Dr. Ferrier, both require clarification. (ECF No. 162, p. 10.) In that regard, petitioner files four new pieces of evidence (ECF No. 163; Exs. 39-42.) Specifically, petitioner files the following: A letter by treating physician, Dr. Ferrier

[2] The four pieces of evidence include three letters and one piece of medical literature. Although the three letters themselves all likely post-date the ruling on entitlement (one letter by Dr. Chu is undated), the record of this case makes clear that petitioner had access to each of these individuals during the entitlement phase of the case. Specifically, two of the letters are by individuals who previously submitted written opinions in the case. (Exs. 8, 16, 21-22.) The third letter is by the author of a study previously cited by petitioner's testifying expert, Dr. Lapp. During the hearing, Dr. Lapp, confirmed in his testimony that he had previously spoken with the author of the letter regarding the specific question addressed in her letter. (Tr. 72.) The newly submitted medical literature, a Report of the CFS/ME Working Group, was published in 2002. (Ex. 41, p. 1.)

(Ex. 39); A letter by Dr. Chu, author of a study discussed in the ruling at issue (Ex. 40); A 2002 Report of the CFS/ME Working Group (Ex. 41); and a letter by petitioner's testifying expert, Dr. Lapp (Ex. 42). Petitioner's motion does not otherwise offer any specific discussion of the procedural history of this case or assert any particular rationale as to why either reconsideration or reopening of entitlement is appropriate. Petitioner has not discussed the legal standard for the relief she seeks or explicitly asserted that any extraordinary circumstance exists. Instead, petitioner's motion is devoted to specific substantive arguments based on the prior ruling's *Althen* analysis, an implicit argument that the ruling at issue suffers a mistake of either fact or law.

In order to better inform the analyses with respect to reconsideration and reopening of entitlement, section (a) of the below discussion examines the potential evidentiary value of each of the four new pieces of evidence. Finding that these four pieces of evidence are not likely to change the outcome, the discussion turns in section (b) to the procedural history of this case and why the interest of justice does not favor the relief petitioner seeks. Finally, section (c) explains why petitioner's legal arguments have not identified any mistake of fact or law that would otherwise warrant reconsideration.

a. Even if considered, petitioner's newly filed evidence would not be likely to change the outcome

As a threshold matter, petitioner must establish that it is appropriate to reopen entitlement to consider these exhibits as a matter of fundamental fairness. As discussed above, the paramount consideration in that analysis is the degree to which the exhibits are relevant and likely to affect the outcome. *See Vant Erve*, 39 Fed. Cl. at 612. For the reasons discussed below, each of the exhibits presented, though broadly meeting the standard for relevancy, are of limited utility and would be very unlikely to change the outcome.

i. Ex. 39 (Dr. Ferrier's letter)

Petitioner asserts in her motion that the opinion of her treating physician, Dr. Ferrier, requires clarification. (ECF No. 162, p. 10.) In addition to her medical records, the ruling at issue also discusses a letter that Dr. Ferrier had provided (Ex. 8) purporting to provide a supporting causal opinion. Petitioner now files a second letter by Dr. Ferrier. (Ex. 39.) This new letter raises several points serving mainly to endorse Dr. Lapp's assessment of petitioner's medical history. Significantly, however, all of these points have the effect of confirming the accuracy of the ruling at issue. Accordingly, it is highly unlikely to change the outcome of the case.

First, Dr. Ferrier confirms that she has reviewed Dr. Lapp's November 2019 evaluation and "[t]he history recorded by Dr. Lapp is accurate. Mrs. Smith does have the diagnoses of fibromyalgia and chronic fatigue syndrome as diagnosed by Dr. Lapp." (Ex. 39, p. 1.) However, ruling at issue already addressed this at least in part. With regard to fibromyalgia, the ruling indicated that "[t]he updated medical records petitioner

filed after the hearing seem to suggest Dr. Ferrier added fibromyalgia to petitioner's problem list in December of 2019 based on Dr. Lapp's assessment." (ECF No. 160, p. 33.) The ruling concluded it was not ultimately necessary to resolve whether petitioner suffered fibromyalgia, but concluded that Dr. Lapp was persuasive in opining that petitioner suffered CFS, which is the operative diagnosis relative to petitioner's causal allegations. (*Id*. at 33-36.) Because the ruling at issue had already accepted Dr. Lapp's diagnostic assessment, Dr. Ferrier's subsequent adoption of that additional diagnosis based on Dr. Lapp's say-so is of no moment.

Second, Dr. Ferrier indicates that petitioner "developed new symptoms of fatigue, fevers and myalgias following her 2012 TdAP vaccination." (Ex. 39, p. 1.) This is also stated in Dr. Ferrier's earlier letter to the court which is addressed and considered by the ruling at issue. (ECF No. 160, pp. 24-25 (quoting Ex. 8).) In the prior letter, Dr. Ferrier discusses these same symptoms and indicates that they can be attributed to her vaccination. (*Id*.) Petitioner stresses that this constitutes Dr. Ferrier's agreement with Dr. Lapp that onset of CFS occurred within days of her vaccination. (ECF No. 162, pp. 6-7.) However, this does not contradict the ruling on entitlement. In addressing *Althen* prongs two and three, the ruling explained that "[p]etitioner received a Tdap vaccination on February 6, 2012, reported unusual symptoms beginning that same night, and sought follow up care rather promptly. Thereafter, Dr. Lapp opines that she developed classic signs of CFS within two weeks. However, upon closer examination of Dr. Lapp's opinion, there is no basis for finding significance in that temporality." (ECF No. 160, p. 45 (internal citations omitted).) Even with the added clarification that Dr. Ferrier agrees with the CFS diagnosis, Dr. Ferrier's new letter addresses only the fact of the apparent onset of symptoms and does not shed any new light on the issues discussed in the ruling's analysis of *Althen* prongs two and three. While Dr. Ferrier's opinion as a treating physician is entitled to weight, the analysis in the decision turned largely on factors relating to the nature of CFS, which is better viewed as Dr. Lapp's domain.

Third, Dr. Ferrier revisits her medical record of January 16, 2012. (Ex. 39, p. 1.) Petitioner stresses that the letter confirms petitioner's symptoms from that illness were "common and transient" and resolved prior to the vaccination. (ECF No. 162, p. 7.) Here, too, however, Dr. Ferrier's new letter only confirms what was already clear in the ruling at issue. Dr. Ferrier confirms that on January 16, 2012, petitioner reported "sore throat, postnasal drip and bilateral ear pain that started 3 weeks prior to presentation. On exam, she was noted to have pharyngeal erythema and pustules. Her symptoms and exam at that time were indicative of infection. She was prescribed clindamycin and Diflucan." (Ex. 39, p. 1.) This merely restates the medical record and is identical to how petitioner's presentation is discussed in the ruling's analysis. (ECF No. 160, p. 49.) Contrary to what petitioner suggests in the instant motion, nothing in the ruling suggests that these symptoms failed to resolve. In fact, the analysis at issue specifically quotes Dr. Lapp's explanation that his opinion was based in part on the fact that the symptoms had resolved. (*Id*. at 49-50 (quoting Tr. 229-30).) The gravamen of the analysis is that Dr. Lapp was unpersuasive in light of his own reliance materials in asserting that infection always leads seamlessly into CFS. (*Id*.) Accordingly, Dr. Ferrier's purported

clarification of her January 16, 2012, record provides no clarification at all and is of little utility.

ii. Ex. 40 (Dr. Chu's letter)

Dr. Lapp's opinion with respect to timing of onset was informed in significant part by a study by Chu et al. The study is discussed at length in the ruling on entitlement. Petitioner now files a letter by Dr. Chu in response to a footnote appended to that discussion. In the ruling at issue, a footnote explains that:

> The Chu paper includes a table that indicates that 10% of subjects identified a medical injection as a factor associated with the onset of their CFS. (Chu et al., *supra*, at Ex. 30, p. 4.) Importantly, however, nothing in the study provides information regarding the time between such injections and onset of CFS. Nor does the study otherwise provide any discussion sufficient to assess the reasonableness of the subjective claim of association. During the hearing, Dr. Lapp indicated that he spoke with Chu and purportedly confirmed that the medical injections at issue mostly referred to vaccination. (Tr. 72.) However, this is not confirmed by the paper itself, and in fact the paper confirms that patients having had a flu vaccination within the preceding four weeks were specifically screened out of the study population. (Chu et al., *supra*, at Ex. 30, p. 2.)

(ECF No. 160, p. 48 n.30.)

In the newly filed letter, Dr. Chu states in full:

> In our 2019 study, "Onset Patterns and Course of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome," 13 out of 132 subjects affected by ME/CFS responded that their illness began with an injection they received at their doctor's office. When questioned about what type of injection, 9 out of the 13 (69%) replied that they were being vaccinated. Four people did not specify/ remember the exact vaccination(s). Otherwise, 2 people reported Hepatitis B vaccinations; 1, Hepatitis B + tetanus; 1, typhoid; and 1, tetanus vaccine.

(Ex. 40.)

Even accepting this additional information at face value, it does not meaningfully change the understanding of the Chu study as discussed in the ruling at issue. Nor does it even address the specific points presented in the footnote regarding the lack of information regarding timing and the lack of sufficient information to assess the reasonableness of the attribution. Notably, Dr. Chu's letter indicates that the data includes four instances, roughly half of the nine subjects reporting post-vaccination CFS, where the vaccine at issue could not be identified because the subject could not recall. This strongly suggests that the history of vaccination was not verified as part of

the study and underscores, rather than resolves, the concern expressed in the ruling on entitlement that there are insufficient details available to assess the reasonableness of the patient's subjective attribution of CFS to the vaccine. Thus, this exhibit is highly unlikely to change the outcome of the case.

iii. Ex. 41 (A Report of the CFS/ME Working Group)

Petitioner presents a 2002 Report of the CFS/ME Working Group for the proposition that medical literature supports the "biological plausibility" of vaccine-caused CFS. (ECF No. 162, pp. 2-5.) This is presented in support of a legal argument by petitioner that she need only present a "biologically plausible" theory of causation pursuant to *Althen* prong one. (*Id*.) However, even assuming the correctness of petitioner's legal argument, mere reference to the term "biologically plausible" would not be the end of any analysis of this literature.

While petitioner is correct that this document characterizes a role for vaccinations as triggers of CFS as "biologically plausible," the actual statement stressed by petitioner is far more equivocal and limited than petitioner lets on. (Ex. 41, p. 32.) First, this statement is based on "a few" unspecified case reports. While case reports are not wholly without evidentiary value, this document presents only reference to the fact of this limited number of case reports. It contains none of the information that would be necessary to assess the value of the specific reports. Second, and relatedly, the report relies only on temporality being established by the case reports and further clouds that reliance by noting that infection may also have played a role. Third, and relatedly, the caution to avoid vaccinations is specifically limited to those suffering infections, suggesting the real-world concern expressed by the working group does not extend to vaccines alone. (*Id*.)

Nor is it clear that consideration of the document as a whole would support petitioner's claim on balance. The same report cautions in a discussion of onset and course of the disease that "[f]actors relating to the development of CFS/ME have been considered as including predisposing, triggering, and maintaining factors, which is conceptually helpful, but is fraught with problems of interpretation and attribution at the level of the individual." (*Id*. at 48.) The report explains that both the etiology (cause) and pathogenesis (disease process) of CFS remain uncertain. (*Id*. at 31.) The report does not even commit to the contention that CFS constitutes a primary disease process. (*Id*.)

In any event, the *Althen* prong one analysis contained in the ruling at issue addresses issues beyond the availability of "a few" case reports. On the whole, while the conclusion of the working group may be entitled to some weight, this exhibit would provide only very minimal support to the causal opinion actually presented by Dr. Lapp. Accordingly, is highly unlikely to change the outcome of the case in light of the ruling's actual analysis of Dr. Lapp's medical theory.

iv. Ex. 42 (Dr. Lapp's letter)

Finally, petitioner seeks to submit a letter by Dr. Lapp. This letter amounts to a supplemental expert report by Dr. Lapp, seeking to restate and revise his opinion now that he has the benefit of the undersigned's analysis. Dr. Lapp states that "I am disappointed in the final opinion and feel that Mr. Horner does not fully understand the ramifications of Chronic Fatigue Syndrome (CFS/ME), apparently misunderstood what I was trying to explain, and misconstrued some of the evidence. As such, I would like to re-state my opinion in different words." (Ex. 42, p. 1.) Dr. Lapp provides a general restatement of his opinion before turning to a list of "specific misunderstandings." However, none of what Dr. Lapp raises in his letter actually identifies any misunderstanding:

- Dr. Lapp takes issue with Dr. He's criticism of his diagram as "severely outdated," noting it was meant only as a simplification for descriptive purposes. (Ex. 42, p. 2.) However, the ruling indicated that Dr. He's criticism was being set aside, explaining that "I assume for purposes of this decision that Dr. Lapp's diagram at Exhibit 33 reasonably depicts the relevant immune response without actually deciding that issue." (ECF No. 160, p. 40, n.24.)

- Dr. Lapp highlights the statement in the ruling that "[t]his underlying immunology speaks to the chronicity of CFS but does not in itself reveal what potential triggers may provoke CFS." (Ex. 42, p. 2 (quoting ECF No. 160, p. 40).) However, Dr. Lapp continues "[t]he point is that any foreign substance – be it a vaccine, a virus, a bacteria, a chrome joint implant, a medication, etc. – can stimulate the immune system in this way. Some elements are more immunogenic than others, obviously." (*Id.*) Setting aside the specifics of his list of stimuli, this purported rebuttal confirms the correctness of the statement quoted from the ruling. Dr. Lapp here underscores both that the immunology being discussed is not specific to any particular trigger and that the various potential triggers are not uniform in their immunogenicity.

- Dr. Lapp states that "I am not at all sure how to respond to Mr. Horner's criticism on Page 41 of the report that, 'Four articles are key to Dr. Lapp's theory – Mu and Sewell (1993), Rook and Zumula (1997), Devnaur and Kerr (2006), and Hardcastle, et al (2015). However, these articles fall short of demonstrating what Dr. Lapp claims they support.'" (Ex. 42, p. 2 (quoting ECF No. 160, p. 41) (internal citations omitted).) Dr. Lapp disputes these articles are "key" to his opinion, but confirms his reliance on them. (*Id.*) Although Dr. Lapp stresses specific points from the articles, he does not identify any error in the ruling's discussion of the papers.

- Dr. Lapp states that the ruling "accepts the argument by Dr. He that immunizations are localized and do not affect the immune system like an infection, which can replicate and spread throughout the body. I am not aware of any support for this notion, which is ridiculous considering the plethora of reports of severe immune reactions following vaccinations." (Ex. 42, p. 3.) This assertion presents two issues. First, it mischaracterizes Dr. He's testimony. Dr. He did not testify that vaccination has no systemic effect. He testified that vaccination and infection have major differences and that vaccines do not include "systemwide immunopathic replication." (ECF No. 160, p. 44 (citing Tr. 285-86, 301-03).) Second, to the extent Dr. Lapp is interpreted as now indicating that it is "ridiculous" to state that immunization is distinct from infection because infection replicates throughout the body, this would constitute a recanting of his own testimony, which is not necessarily credible.[3]

- Dr. Lapp also includes brief discussion of *Althen* prongs two and three; however, these points merely restate aspects of the case that were already thoroughly addressed by the ruling.

On the whole, Dr. Lapp's letter merely expresses disappointment with the outcome. He has not raised any point that is concerning for error or omission in the ruling at issue. Nor has he provided any new information that would affect the complained of analysis. Accordingly, Dr. Lapp's letter is highly unlikely to affect the outcome of this case.

It should also be noted that Dr. Lapp's letter does nothing to tie together the evidentiary value of the three other pieces of evidence. As discussed above, each individual piece of evidence fails on its own to represent evidence that would affect the outcome. It is also the case, however, that all four of these exhibits considered collectively likewise fail to offer meaningful evidence that would be likely to change the outcome. This is *not* a scenario in which the whole is greater than the sum of its parts.

b. The interest of justice does not favor the relief petitioner seeks

Petitioner's request to reopen the record and reconsider entitlement rests on a purported need to "clarify" the opinions of Drs. Ferrier and Lapp. (ECF No. 162, p. 10.) However, the procedural history of this case disfavors this relief.

[3] With regard to the point at issue, the ruling specifically noted Dr. Lapp's testimony at page 211 of the transcript. (ECF No. 160, p. 44.) Dr. Lapp was asked on cross-examination, "The Tdap vaccination is not biologically equivalent to a live infectious agent, correct?" He answered, "That's correct." He was then asked "Tdap cannot reproduce itself inside the human body, correct?" He answered, "As far as I know, yes." Subsequently asked to confirm that "[t]he immune system responds differently to a live infection than it does to the Tdap vaccine," Dr. Lapp opined "I can't say that. I can't say that one way or the other, but I'm not sure you could say it's different."

Special masters are tasked with "endeavoring to make the proceedings expeditious, flexible, and less adversarial, while at the same time affording each party a full and fair opportunity to present its case and creating a record sufficient to allow review of the special master's decision." Vaccine Rule 3(b)(2). The special master must receive and consider all relevant evidence "governed by principles of fundamental fairness to both parties" (Vaccine Rule 8(b)(1), but is given the discretion to "determine the format for taking evidence and hearing argument based on the specific circumstances of each case and after consultation with the parties" (Vaccine Rule 8(a)).

All of these precepts have been followed in this case and petitioner has been provided a full and fair opportunity to present her case. Petitioner has not asserted otherwise. In fact, petitioner's motion offers no specific argument addressing the "interest of justice" standard at all. There are circumstances where fundamental fairness dictates reopening of the evidentiary record. *See Horner*, 35 Fed. Cl. at 27. However, the "paramount" test for reopening the record is an examination of the evidence to be added to the record. *Vant Erve*, 39 Fed. Cl. at 612. Here, for the reasons discussed in section (a) above, it is unlikely that the newly filed evidence would change the outcome. Thus, petitioner's burden with respect to the delay and prejudice caused by her late filing "increases dramatically." *Id.*

As explained in the ruling at issue, this case has been litigated over an extended period. (*See* ECF No. 160, pp. 3-6.) In that regard, Dr. Ferrier's contemporaneous medical records have been a part of the record of this case literally for years. Petitioner also previously filed a letter by Dr. Ferrier supporting vaccine-causation November 14, 2016. (ECF No. 55; Ex. 8.) Subsequent to the hearing, petitioner was ordered to file updated medical records and this included medical records from Dr. Ferrier. (ECF Nos. 143, 146; Exs. 37-38.) All of these materials were thoroughly addressed in the ruling at issue. Furthermore, petitioner was previously put on notice regarding the assigned special master's concerns regarding the adequacy of Dr. Ferrier's causal opinion letter and provided an opportunity to file a more detailed report. (ECF No. 56.) After petitioner failed to produce a further clarifying report the special master issued an order to show cause why the case should not be dismissed (ECF No. 62) and petitioner filed a response indicating that "[a]lthough further information from Dr. Ferrier may help clarify some issues in this case, it is not necessary for this case to move forward" (ECF No. 63, pp. 1-2). Petitioner did not subsequently file any further opinion from Dr. Ferrier prior to the close of the entitlement phase of this case and, instead, filed reports by Dr. Lapp.

After this case was remanded for further proceedings in December of 2018, petitioner was permitted a year and a half to develop her expert's opinion prior to the scheduling of an entitlement hearing. (ECF No. 106-121.) After petitioner filed an initial report from Dr. Lapp (ECF No. 113; Ex. 16), petitioner was allowed additional time to schedule an in-person evaluation with her expert. She was then permitted to file a second report by Dr. Lapp and then filed a third report by Dr. Lapp responding to respondent's experts' reports. (ECF Nos. 115, 121; Exs. 21-22.) Further still, the

undersigned permitted petitioner to file additional medical literature just prior to the hearing, out of time and over respondent's objection. (ECF No. 140.) During the hearing, Dr. Lapp cited still further unfiled literature during the hearing and used an unfiled demonstrative. Petitioner was permitted to file those materials into evidence as well. (ECF No. 143.) During the hearing, the court was actively engaged to ensure the clarity of Dr. Lapp's testimony. (Tr. 182-83, 189, 192, 194-95, 214, 223-24.) Additionally, Dr. Lapp sat for a court examination (Tr. 229-42) and petitioner presented rebuttal testimony by Dr. Lapp after respondent had presented his case (Tr. 306-09).

Thus, petitioner has clearly been provided a full and fair opportunity to develop and present her proffered opinion evidence from both Dr. Ferrier and Dr. Lapp. In fact, it is difficult to see how petitioner could have been accommodated further. Moreover, though she disagrees with the outcome of the ruling on entitlement, petitioner does not suggest that any aspect of the complained of analysis was beyond the scope of what was litigated by the parties. And, in fact, as discussed above, Dr. Lapp fails to articulate any error or omission in the ruling. His supplemental report represents nothing more than the hope for a second bite at the apple whereas motions for reconsideration are "not intended to give an unhappy litigant an additional chance to sway the court." *Prati*, 82 Fed. Cl. at 376 (2008) (quoting *Fru–Con Constr. Corp.*, 44 Fed. Cl. at 300). To the extent petitioner merely disagrees with the outcome, her rights and interests are instead protected via the procedures for a Motion for Review. Vaccine Rules 23-28. Considering the substance of petitioner's new submissions and the procedural history above, petitioner has not demonstrated that reconsideration or reopening of entitlement is necessary to prevent any type of injustice, manifest or otherwise.

Nor is it the case that the relief petitioner seeks would be without negative consequences if it were granted. In keeping with fundamental fairness to both parties (Vaccine Rule 8(b)(1)), accepting petitioner's proposed new evidence would require providing respondent an opportunity to respond. This would result in delay in itself – a delay clearly caused by the petitioner – and could also open the door to a proliferation of proposed new evidence from both parties. Additionally, because Dr. Lapp's supplemental report purports to restate to his own testimony and appears in part to recant certain testimony, respondent would have a clear interest in seeking further cross examination to explore what would be a credibility issue. Thus, the possible need for a further entitlement hearing to prevent prejudice to respondent cannot necessarily be excluded. Prolonged delay and/or prejudice to respondent are not an inevitably in this case; however, judicial economy disfavors the relief petitioner seeks given that entitlement was resolved fairly in the first instance. In that regard, this program's crushing caseload should not be discounted. Given the thousands of petitions pending, this program's resources could be focused on more pressing needs.

This order does not accept the premise that either Dr. Ferrier's or Dr. Lapp's opinions were in need of clarification, or that the ruling at issue has misunderstood either. However, the procedural history of this specific case also counsels that

petitioner has been given ample opportunity to remedy any shortcomings in the causal opinions offered in this case. As the Court of Federal Claims indicated in *Sword v. United States*: "What trial attorney worth his or her salt would not try a case a bit differently once counsel knew what the fact-finder found important within the body of evidence? But fairness does not require that we accede to this all-to-human desire." 44 Fed. Cl. 183, 191 (1999).

Accordingly, reconsideration is not in the interest of justice and petitioner's motion should not be granted pursuant to Vaccine Rule 10(e). Nor is a reopening of the record necessary to maintain fundamental fairness in the receipt of evidence in this case.

c. Petitioner's legal arguments are not persuasive

Finally, regardless of all of the above, if the ruling at issue includes a material error of fact or law, reconsideration could be warranted. In that regard the bulk of petitioner's motion is dedicated to legal analysis under the three *Althen* prongs for determining causation-in-fact. However, to the extent the motion for reconsideration implicitly relies upon the assertion of a mistake of fact or law, it is also the case that petitioner's substantive legal arguments are unavailing.

i. *Althen* prong one

Petitioner argues with respect to *Althen* prong one that "[t]he *Althen* Court was clear that Prong One was satisfied by a plausible medical theory causally connecting a vaccine to an injury. *Althen* has never been overruled." (ECF No. 162, p. 3.) Petitioner notes that the ruling at issue accepted that CFS "may involve an aberrant chronic immune response and that CFS symptoms may be cytokine-related." (*Id*. (quoting ECF No. 160, p. 43).) Petitioner contends that medical literature shows that immunizations in rare circumstances can cause cytokine dysregulation. In support of this argument, petitioner files a new exhibit – "A Report of the CFS/ME Working Group" (Ex. 41) – which she quotes as indicating that

> A few case reports have suggested that CFS/ME has occurred after immunisations, though intercurrent events, including infection, might have played a part in the disease process. It is biologically plausible that some processes seen after infections could also occur after immunisations, but this has yet to be confirmed by a good quality cohort study in the case of CFS/ME.

(ECF No. 162, p. 4 (quoting Ex. 41, p. 32).)

Petitioner also argues by citation to a previously filed article by Devanur et al. (Ex. 17) that various vaccines, including the tetanus vaccine at issue in this case, are implicated as triggers of CFS. (ECF No. 162, p. 4 (quoting Ex. 17, p. 7).) Petitioner

further cites Dr. Lapp's discussions with Lily Chu, author of a previously filed article (Ex. 30), as confirmation that the study implicates the Tdap vaccine. (ECF No. 162, pp. 4-5.) Petitioner newly files with this motion an undated letter by Dr. Chu to that effect. (Ex. 40.) Thus, petitioner argues that she has presented preponderant evidence of a biologically plausible theory linking the Tdap vaccine to CFS. (ECF No. 162, p. 5.)

It is not necessary to parse petitioner's specific understanding of the *Althen* decision. While the *Althen* Court stressed that a petitioner may prove causation circumstantially, the Federal Circuit has also repeatedly held that cause-in-fact claims must be supported by "sound and reliable" medical or scientific explanation. *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994); *Boatmon v. Sec'y of Health & Human Servs*., 941 F.3d 1351,1360-61 (Fed. Cir. 2019); *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1384-85 (Fed. Cir. 2021). Petitioner is correct that *Althen* has not been overruled, but nor has it been contradicted. *Kottenstette v. Sec'y of Health & Human Servs.*, 861 Fed. App'x 433, 441 (noting of the *Knudsen* holding regarding "specific biological mechanisms" that "*Boatmon* did not, and indeed, could not, overrule these previous articulations of the standard for causation"); *but see Simanski v. Sec'y of Health and Human Servs.*, 671 F.3d 1368, 1384 (Fed. Cir. 2012) (specifically explaining that while petitioner need not identify a specific biologic mechanism, causation must also be supported by "sound and reliable medical or scientific explanation"). As the Federal Circuit explained in *Knudsen*, "[c]ausation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast *per se* scientific or medical rules." 35 F.3d at 548.

Here, citing the above-discussed caselaw, the ruling at issue explained that petitioner's burden was to present a theory that was legally probable rather than scientifically certain and that is supported by sound and reliable explanation. (ECF No. 160, p. 39.) The ruling stressed that petitioner need not present either literature or a specific mechanism. (*Id*.) Applying that standard, the ruling addressed in detail why Dr. Lapp's explanation was unpersuasive, both because he oversold the value of the literature he himself had relied upon and because his own testimony was not persuasive with regard to a key point. The fact that petitioner has belatedly filed an article that uses the term "biologically plausible" would not be dispositive in itself. Nor does it suggest that the ruling applied an incorrect burden of proof or otherwise misconstrued the evidence. Petitioner's further arguments relating to cytokine dysregulation and aberrant immune response are answered by the analysis already contained in the ruling at issue.

ii. *Althen* prong two

Quoting *Andreu v. Secretary of Health and Human Services*, petitioner stresses that "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect shows that the vaccination was the reason for the injury." (ECF No. 162, p. 5 (quoting 569 F.3d 1367, 1375 (Fed. Cir. 2009).) Petitioner charges that "[t]he Ruling takes issue with the fact that none of Mrs. Skinner-Smith's

treating doctors diagnosed her with CFS close to the time of the vaccination." (*Id*. at 5-6.) Petitioner argues that it is irrelevant whether the treating physicians could identify petitioner's condition as CFS if they attributed her symptoms to her vaccine. (*Id*. at 6.)

Importantly, however, the Vaccine Act requires special masters to consider treating physician opinions based on the record as a whole rather than blindly accept the views of the treating physicians in isolation. Section 13(b)(1) provides that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court." Petitioner's motion for reconsideration is silent as to *how* the treating physician opinions support Dr. Lapp's opinion. Contrary to what petitioner argues in her motion for reconsideration, the opinions of the treating physicians have been considered in the ruling at issue. However, they are not consistent with Dr. Lapp's opinion. The ruling at issue explained:

> Petitioner was never diagnosed with CFS by any of her treating physicians prior to consulting Dr. Lapp. Accordingly, while the treating physicians felt a vaccine reaction was possible, they did not offer any contemporaneous opinion that petitioner suffered vaccine-caused CFS. Instead, petitioner's claim is based entirely on Dr. Lapp's hindsight. Taking petitioner's symptoms and the close temporal relationship to vaccination, the treating physicians were willing to opine that petitioner was suffering an adverse vaccine reaction in the form of a likely serum sickness. (Ex. 1, p. 706; Ex. 3, pp. 1-3.) Dr. Lapp, however, has opined that petitioner never suffered any serum sickness reaction. Instead, he opines that the symptoms the treating physicians identified as serum sickness were actually symptoms of the CFS itself. (Tr. 230.) Moreover, even if petitioner did suffer a temporary serum sickness that explains her initial symptoms, Dr. Lapp further opined that "I have never known serum sickness to lead to chronic fatigue syndrome." (Tr. 231.) Additionally, to the extent he opined that petitioner suffered a vaccine-caused cellulitis, he also opined that the cellulitis would not have caused petitioner's CFS. (Tr. 212.) Thus, Dr. Lapp rejects either cellulitis or serum sickness as part of the relevant causal chain, thereby dismissing any causal connection between petitioner's CFS and any illness documented in the medical record that may have in turn been causally connected to the vaccination.

(ECF No. 160, p. 46.)

By and large the treating physicians opined that petitioner's symptoms were caused by her vaccine *based upon their own diagnosis* of a serum sickness. (Dr. Ferrier being the notable exception who originally provided no diagnosis to support her opinion as explained in the ruling at pages 29-30.) However, Dr. Lapp opined on petitioner's behalf that their diagnosis was incorrect and based his causal opinion on the presence of a different condition, CFS. Moreover, the ruling concluded that there is not preponderant evidence that petitioner suffered a serum sickness based in significant

part on the strength of Dr. Lapp's testimony. (See ECF No. 160, pp. 29-30.) Accordingly, petitioner directly and fatally undercut the actual causal assessment of most of the treating physicians. Conversely, as the ruling noted, the treating physicians did not diagnose CFS. This fact was not fatal to petitioner's claim insofar as the ruling credited petitioner as suffering CFS based on Dr. Lapp's opinion; however, petitioner cannot reasonably interpret the treating physicians' statements as recognition that her vaccine caused a condition they did not know she had.

iii. *Althen* prong three

With regard to *Althen* prong three, petitioner stresses Dr. Lapp's experience in treating patients with CFS and contends that the ruling discounts that experience. (ECF No. 162, p. 7.) Petitioner argues that the literature confirms that a significant number of CFS sufferers experience a quick onset. (*Id*. at 8.) Petitioner stresses "[t]he pertinent question is what is possible." (*Id*.) Petitioner also takes issue with discussion in the ruling of a sore throat approximately three weeks before the vaccination.[4] (*Id*. at 8-9.) Petitioner argues that

> to suggest that a past sore throat might be causative violates 42 USCA § 300aa-13. In general, compensation cannot be made if an injury is due to factors unrelated to vaccination. Critically, "the term 'factors unrelated to the administration of the vaccine' – (A) does not include any idiopathic, unexplained, unknown, hypothetical, or uncommentable cause, factor, injury, illness, or condition.

(ECF No. 162, p. 9.) Petitioner argues that she is not obligated to eliminate alternative independent potential causes. (*Id*. (quoting *Walther v. Sec'y of Health & Human Servs*., 485 F.3d 1146, 1152 (Fed. Cir. 2007).)

Petitioner's argument misconstrues the ruling. Petitioner's reliance on Dr. Lapp's prior clinical experience in preference to the Chu paper is misplaced. As the ruling explains, "[d]uring the hearing Dr. Lapp confirmed that he felt the Chu study supported his theory vis-à-vis timing." (ECF No. 162, p. 48 (citing Tr. 238-39).) Additionally, petitioner's focus on Chu et al. as evidencing "quick onset" is misleading. As explained in the decision, the Chu study focuses largely on "abrupt" versus "gradual" onset of CFS. Especially with respect to injections, the study lacked information regarding the time interval between injections and onset of CFS. (*Id*. at 48-51, n.30.)

[4] In her motion, petitioner repeatedly refers to her preceding illness as merely a "sore throat" and characterizes it as idiopathic. (ECF No. 162, pp. 8-9.) This mischaracterizes the record. While petitioner did have a sore throat, the record confirms for reasons discussed throughout the ruling that petitioner's illness was not limited to a sore throat. In fact, even in petitioner's newly submitted letter by Dr. Ferrier she confirms that petitioner's "symptoms and exam at that time were indicative of infection." (Ex. 39, p. 1.)

Additionally, the ruling did not require petitioner to disprove a causal connection to her prior infection. Nor did the ruling find that the infection and vaccination may have acted in conjunction to cause petitioner's CFS as petitioner asserts. The ruling explained that "[b]oth the Evans and Chu articles explain that the so called 'succumbing' to CFS is not the same as onset, which may in fact occur nascently much earlier. In that regard, the actual onset of petitioner's CFS is not clear." (ECF No. 160, p. 50.) The ruling further explained that

> Even if there is the appearance of a temporal relationship here, Dr. Lapp has little basis for selecting petitioner's vaccination as the starting point of a logical sequence of cause and effect to suggest, pursuant to *Althen* prong two, that her vaccination caused her CFS. Nor has he persuasively addressed pursuant to *Althen* prong three what would constitute an appropriate temporal relationship between onset of CFS and an antecedent trigger. The Evans and Chu papers, coupled with Dr. Lapp's own testimony, suggest that the medical community's understanding of the onset of CFS lacks the degree of understanding or precision Dr. Lapp would need to pinpoint the actual onset of her condition and/or distinguish petitioner's vaccination as the initiating cause of her CFS.

(*Id*. at 51.)

III. Conclusion

For all the reasons discussed above, petitioner's motion for reconsideration of the August 15, 202 Ruling on Entitlement (at ECF No. 160) is **DENIED**. Petitioner's status report as ordered by the Damages Order at ECF No. 161 remains due by September 14, 2022.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master